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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,788	01/28/2005	Yoshiharu Yamazaki	OGA-012	1737
20374	7590	10/16/2009	EXAMINER	
KUBOVCIK & KUBOVCIK SUITE 1105 1215 SOUTH CLARK STREET ARLINGTON, VA 22202			PEFFLEY, MICHAEL F	
			ART UNIT	PAPER NUMBER
			3739	
			MAIL DATE	DELIVERY MODE
			10/16/2009 PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/522,788

**Applicant(s)**

YAMAZAKI ET AL.

**Examiner**

Michael Peffley

**Art Unit**

3739

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 10-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-6-8-10-12-15-17-18 and 21-33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14, 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 2-5, 13, 16, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Applicant's amendments and comments, received June 8, 2009, have been fully considered by the examiner. Claims 1, 6-8, 10-12, 15, 17, 18 and 21-33 remain withdrawn from further consideration, and claim 9 has been canceled. The following is a complete response to the June 8, 2009 communication.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5, 13, 16 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall (4,946,440) in view of the teachings of Lennox et al (4,955,377) and Wijay et al (4,921,483) and further in view of the teaching of Strul (5,498,261).

Hall discloses a catheter comprising a double cylinder structure having an inner shaft (16) slidably inserted into an outer shaft (12). A balloon (18) is attached between the tip portion of the inner shaft and the tip portion of the outer shaft (Figures 3 and 4), and Hall disclose a HF wire (86) provided inside the balloon. Hall fails to specifically disclose the use of two electrodes, providing a temperature sensor in the balloon, or the particular tube attached to the inner shaft and being softer than the inner shaft.

Regarding the use of multiple electrodes and temperature sensors, the examiner maintains that it is generally known in the art to provide bipolar electrodes and temperature sensors in RF balloon devices. Lennox et al disclose an analogous RF balloon catheter device and specifically teach that it is known to provide a pair of

electrodes (22,24) within a balloon device, and further disclose the use of a temperature sensor (26) for monitoring temperature and controlling the delivery of RF energy.

Regarding the provision of a soft tip attached to the inner shaft, Wijay et al disclose another catheter for angioplasty procedures and teach that it is advantageous to provide the distal end of the catheter with a tube (T - Figure 4) that is softer than the inner shaft (Abstract) and that extends from the inner shaft to provide a safer distal end for introduction through the vasculature.

Regarding the location of the temperature sensor, Strul discloses an analogous RF heating balloon for angioplasty and specifically disclose a temperature sensor (20) carried by the electrode member (18) as shown in Figure 2. Strul further discloses the use of multiple sensors (22) located at different locations on the balloon, and to have provided a sensor at any desired location (e.g. a tip) would have been an obvious consideration for one of ordinary skill in the art to receive thorough temperature information across the balloon.

Regarding claims 3-5, Wijay et al also disclose a side-hole in the tube (Figure 6), as well as the use of various copolymers for making the tube (col. 10, lines 19-21). The particular hardness gradient and the recovery rate of the material are deemed to be obvious design parameters for those of ordinary skill in the art.

Regarding claim 13, the specific inductive capacity of the shafts and the lead coatings are deemed to be within the purview of the skilled artisan.

To have provided the Hall device with two electrodes and a temperature sensor in the balloon member for heating the balloon and controlling the delivery of energy,

respectively, would have been an obvious design modification for one of ordinary skill in the art in view of the teaching of Lennox et al. To have further provided the Hall et al device with a soft tube extending from the inner shaft to provide for safe introduction of the device through the vasculature would have been an obvious modification for the skilled artisan in view of the teaching of Wijay et al. The exact location for the temperature sensor would have been an obvious design selection for the skilled artisan since Strul fairly teaches such locations for temperature sensors in an analogous balloon device.

***Allowable Subject Matter***

Claims 14, 19 and 20 are allowable over the prior art of record.

***Response to Arguments***

Applicant's arguments filed June 8, 2009 have been fully considered but they are not persuasive.

Applicant asserts on page 16 of the response that Lennox fails to disclose the use of a temperature sensor in the location as now specified in claim 2 and newly added claim 34. The examiner maintains that Lennox was never cited as disclosing the specific location of the temperature sensor. The subject matter added to claim 2 is the same subject matter found in original (now canceled) claim 9. The examiner had used the Strul reference to show the various known locations that one of ordinary skill in the art would locate a temperature sensor in an analogous balloon device. Applicant has not substantively argued the merits of the rejection of claim 9. The examiner maintains

that the Strul reference remains a valid teaching to the skilled artisan of the known, obvious locations for temperature sensors and that the combination of references fairly meets the rejected claims.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/  
Primary Examiner, Art Unit 3739

/mp/  
October 14, 2009